(12)

EUROPEAN PATENT APPLICATION

21) Application number: 89310572.6

(51) Int. Cl.5: A61F 2/44

22) Date of filing: 16.10.89

The title of the invention has been amended (Guidelines for Examination in the EPO, A-III, 7.3).

- @ Priority: 17.10.88 US 259031
- 43 Date of publication of application: 23.05.90 Bulletin 90/21
- Designated Contracting States:
 DE FR GB NL SE

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- 54 Fusion cage for bone joints.
- © A fusion basket (10) having an external, substantially continuous helical V-thread (12) by which it can be screwed into a bore after first forming in the bore mating female threads that bite into the cancellous regions. Mating of the threads ensures that the fusion basket remains securely in place without compressing or splitting the recipient bone. Eventually, the ingrowth of bone through perforations (13) in the valley (14) of the thread forms a permanent interconnection between the two bony structures. When used to create bone ingrowth between adjacent vertebrae, the V-thread fusion basket is implanted in pairs on opposite sides of the disc space.

Fig.1

FUSION CAGE

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The invention concerns method and apparatus for fusing two adjacent bony structures such as a bone joint, especially adjacent vertebrae of the spine.

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BACKGROUND OF THE INVENTION

Subsequent to injury, disease or other degenerative disorder, the disc, a ligamentous cushion between vertebrae, may undergo a painful deterioration. The disc shrinks and flattens out, and the distance between the vertebral bodies begins to collapse. Subsequently, there may be a progressive degeneration leading to mechanical instability, where painful translocations occur between adjacent vertebrae. The movement-induced pain may be so disabling that in many such cases, the segmental motion must be eliminated. Thus, rigid fusions may be the only present means to stop the translocations and relieve the pain.

It is generally held that successful fusions demand a contiguous growth of bone to create a solid mass that will unite the movable elements into one unit. Otherwise, the fusion cannot achieve the tasks of pain reduction, maintenance of intervertebral height, and immobility of the segment. When fusion bone is first placed, it is soft and movable, having no cohesive strength. Therefore a variety of appliances have been developed that attempt to hold the segments quite still under conditions of normal spinal activity and daily stress. Bone graft material is placed between the segments, the outer or cortical surfaces of which have been removed or deeply scarified so as to promote the ingrowth of the graft into these recipient sites. Thus positioned, the bone graft slowly unites the segments. Such an appliance is not meant to permanently secure immobility of the segments. Bone ingrowth is required for this.

Dependency upon such an appliance as the sole stabilizer is ultimately unsuccessful due to the development of a mechanical gap or transition between the bone and the appliance, leading to structural failure of the bone and adjacent connective tissue. Such failure is seen in fractures, erosion, and absorption of bone with potential further collapse. The pain may also become progresively disabling.

Approximately 150,000 lumbar spinal fusions were performed in the USA during 1987, as reported by the American Hospital Association. There are many methods for intervertebral fusion. The most successful have achieved a success rate of

about 90% in random cases. However, several of these techniques, especially those requiring complex appliances, are difficult to master and are hazardous to nerve and vessel structures normally lying close to the involved bones.

From a biomechanical point of view, the most important location of a spinal fusion is at the mechanical center of rotation between the vertebrae. This point is centered within the disc space. Therefore, an interbody fusion is the most rigid and thus the most sought after method among surgeons. Current methods of interbody fusions are, however, the most hazardous of all spinal fusion methods.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions. Typically, a plug, dowel, or segment of bone is driven tightly into a cavity carved inside the interbody, intradiscal space. Since there must be a bone-to-bone bridge created during the fusion process, connective tissue and discal tissue must be removed. Therefore, deep cuts within the bone must penetrate into the softer, cancellous region to promote bone growth across the space.

Intervertebral fusions using circular bone grafts have been reported in the orthopedic and neurosurgical literature for some years. B. R. Wiltberger in a paper published in Clinical Orthopedics, Vol. 35, pp. 69-79, 1964, reviewed various methods of intervertebral body fusion using posterior bone dowels driven firmly into a suitably smaller hole between the adjacent vertebrae. Upon doing so the dowel can split or crack or collapse. The stretched bone might also split and it can be compressed by the dowel to the point that it will not grow normally due to collapse of formerly open pores or vascular channels. If this occurs, there may be a late absorption of surrounding bone and the dowel might loosen, with a renewed danger of expulsion. See also a two-page brochure from Neurological Surgery Associates of Cincinnati, Inc. entitled "Posterior Lumbar Interbody Fusion Made Simple" which shows, after the bone dowel placement, the "(a)pplication of 5 mm dacron suture around spinous processes."

U.S. Patent 4,501,269 (Bagby) describes a surgical procedure for stabilizing the cervical spine of a horse and says that the procedure "is applicable to any human or animal joint formed by opposed contiguous bony surfaces which are covered and separated by intervening cartilage and are surrounded by ligaments which resist expansion of the joint. Specific examples of such joints are a spinal joint between adjacent vertebrae or the ankle joint. The process was developed to immediately stabilize the joint and to further promote ultimate

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bone-to-bone fusion...The implanted structure is in the form of a perforated cylincrical bone basket which can be filled with bone fragments produced during the preparation of the joint. These bone fragments provide autogenous tissue to promote bone growth through the basket, as well as around it

"The process involves the initial steps of surgically accessing the joint and removing intervening cartilage located between the contiguous bony surfaces. A transverse cylindrical opening is then bored across the contiguous bony surfaces. Immediate stabilization is achieved by driving into the cylindrical opening a hollow basket having a rigid perforated cylindrical wall whose outside diameter is slightly greater than the inside diameter of the cylindrical opening. The implanting of the basket spreads the bony surfaces apart in opposition to the resistance to expansion of the joint provided by the surrounding ligaments." (Col. 2, lines 26-55).

Vich, J. Neurosurg Vol. 63, pp. 750-753 (1983) describes a means for cervical spine fusion, using an anterior approach, by surgically implanting a cylindrical bone graft. "Screw threads are placed in the graft with a small, previously sterilized die. The grooves of the thread can be made as deep as required. The vertebral cervical bodies are prepared according to Cloward's technique. After a cylindrical bed has been drilled in the appropriate intervertebral bodies, the graft is screwed into place with instruments especially developed for this purpose." (P. 750). The Fig. 2 legend points out that a threaded graft dowel has a larger contact surface than a plain dowel and a greater resistance to pressure and sliding.

An additional desirable effect of an intervertebral fusion is the restoration or maintenance of a normal intervertebral spacing. Spreading devices are generally required in order to restore all or a part of the normal intradiscal height, in the process of placing the fusion material or applicance. When the procedure is performed using the commonly employed posterior approach, a variety of spreaders may be placed between various posterior bony elements normally attached to he vertebrae, such as, dorsal spinous processes or laminas. Using such spreaders, a forward tilt or wedging of the discal space occurs, with the posterior aspect of the space becoming more open than the anterior. When a bone graft of any shape is driven into a cavity that is wedged more open posteriorly between two opposing movable vertebrae, there is a strong propensity for the graft to be retropulsed during the postoperative recovery period as a result of to and fro movement between the opposing vertebrae. Thus, to aid in the prevention of graft expulsion, it would be desirable to have the cavity either maintain parallelism or be slightly narrower at its most posterior portion. Ventral to this cavity, the stout ligamentous disc anulus remains and prevents ventral migration of the graft into the retroperitoneal space. Further, there is value in restoring the original spinal lordotic curve, as the fusion grows; this requires that the cavity and the interbody fusion element be placed to promote a normal spinal anatomical position, that is, without wedging of the space in either direction.

BRIEF SUMMARY OF THE INVENTION

The invention provides a fusion basket or cage which, like the fusion basket of Bagby, is a perforate rigid cylinder that can be surgically inserted into a bore that has been formed in two adjacent bony structures such as two vertebrae. The fusion cage is then packed with bone chips or other boneinducing substance, thus inviting ingrowth of live bone. The fusion cage of the invention differs from the fusion basket of Bagby by an external, substantially continuous helical V-thread by which it can be screwed into the bore, after first forming mating female threads in the bore. Mating of the threads ensures that the fusion basket remains securely in place, there being much less danger of splitting or compression atrophy of the recipient bone. Eventally, the ingrowth of bone through perforations in the valley of the thread forms a permanent interconnection between the two bony structures.

By V-thread is meant that the crown of the thread is sharp, although its valley preferably is blunt or rounded to permit the mating peaks of the female threads to have adequate strength. When the angle of the V-thread at its crown is about 60, a preferred range of radii for the fillet in the valley is from 0.35 to 0.75 mm. The angle at the crown of the V-thread should be no more than 90°, because a sharper thread would increase the exposed interface surface of bone relative to the implant, thus increasing the opportunity for ingrowth. However, the angle at the crown should be at least 45°, because the pitch would be undesirably small if the angle were smaller. An unduly small pitch would entail weak female bone threads and create a danger of cross threading.

The perforations should be as large as possible as long as the fusion basket has adequate structural strength. When the surface of the fusion basket is projected onto the inner face of a cylinder, the projected perforations should comprise from 30% to 60% of the projected area, preferably about 50%. Individual apertures should be at least one mm both axially and transversely to permit good ingrowth of fresh bone, whereas the fusion basket might be unduly weakened if the apertures were

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substantially more than 2 mm axially and 3 mm transversely when the angle of the V-thread at its crown is about 60°.

The novel fusion basket preferably is fitted with end caps, a first of which may be in place before the fusion basket is screwed into the recipient bone, and thus should have a maximum diameter no greater than the minor diameter of the V-thread of the fusion basket. The first end cap retains the bone-inducing sustance when it is packed into the fusion basket. The open end of the fusion basket may then be closed with a second end cap to hold the bone chips securely in place. The end caps may be imperforate but preferably have substantially the same perforation as does the fusion basket to permit bone or other tissue ingrowth through the end caps. However, end caps may not be necessary or, if used, they can be made of biodegradable material, even when the fusion basket is not.

Currently the novel V-thread fusion basket preferably is made of implantable-grade stainless steel. Titanium and ceramics are also useful, as are super-strength polymers or composites of polymers and high-strength filaments such as superhigh-density polyethylene, glass, or graphite. Nonmetallic composites have the preferred ability to pass x rays or magnetic beams without distortion, thus enhancing the preparation of scan images as compared to metallic fusion baskets. The fusion basket can be biodegradable, because it no longer is needed after the bone ingrowth has matured. When the fusion basket is not biodegradable, it can remain in place permanently after the ingrowth has taken place, in contrast to the need to remove many types of metallic supports or appliances that have heretofore been used to promote rigid fusions.

Useful bone-inducing substances include bone chips and bone substitutes or synthetic material, with or without bone activating matter, such as hydroxyapatite, bone morphologic protein, bone growth factor, or cartilage activation factor. Instead of being mixed with the bone-inducing substance, bone-activating matter can be coated onto the novel fusion basket, e.g., after being microencapsulated in a wax. When the fusion basket is made of an organic material, bone activating matter can be combined with the organic material before it is formed into the fusion basket.

For implantation between vertebrae of a person's lower back, two sizes of the novel fusion basket should suffice, one having a V-thread major diameter of 16 mm and the other a major diameter of 12 mm. Because the anterior-posterior dimension of a typical lower lumbar vertebra is about 30 mm, the length of the fusion basket preferably does not exceed 25 mm but is at least 20 mm in

length to give sufficient contact as well as a good platform when implanted in pairs.

The crown of the V-thread of the novel fusion basket preferable is continuous, both for strength and for ease of insertion into the threaded bore. Preferably the V-thread has from 3 to 8 turns per cm. A smaller turn ratio may result in an undesirably large thread depth, penetrating too deeply into the cancellous bone. A larger turn ratio may unduly restrict the size of the performations.

The novel V-thread fusion basket can be implanted for fusing adjacent bony structures by the following method: (a) forming ain said bony structures a bore with a female thread that penetrates into their cancellous regions, (b) forming a rigid, perforate, cylindrical basket to have an external, substantially continuous helical V-thread that can mate with said female thread, (c) screwing the basket into said threaded bore, and (d) packing the basket with bone-inducing substance. When the bore to be formed in step (a) is to extend between adjacent vertebrae, there should be prior to step (a) the added step of spreading the vertebrae apart, preferably in a manner that maintains their parallelism, the fusion basket is implanted in pairs on opposite sides of the disc space.

The novel fusion basket should have a modulus of elasticity approximating that of the recipient bone, thus permitting it to flex along its length, consequently minimizing stresses at the bony interface between the graft and recipient bone. Although a fusion basket of substantially lower modulus of elasticity would provide the same desirable result, it might not have adequate structural strength.

The bore into which the V-thread fusion basket is to be inserted preferably is tapped by hand, using a slow motion to ensure against burning the bone. This freshens the bone margins of the bore so that if any bone had been burned by drilling to form the bore, it is now cut away slowly by hand. The tapping process is quite safe, in that the surgeon can feel the progress of the technique.

The V-thread fusion basket preferably is screwed by hand into the threaded bore, again permitting the surgeon to feel if the resistance is too great and that rethreading of the bore might be required. In contrast, a bone dowel typically is driven into a bore using a hammer, and in order to guard against an overly tight fit, the surgeon listens to the sound of the striking hammer and also monitors the degree of resistance.

When using the noval fusion basket to creat bone ingrowth between adjacent vertebrae, the fusion basket should be implanted in pairs on opposite sides of the disc space. Each is held in place by its V-thread, biting into female threads that penetrate into the cancellous bone of the inter-

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posed vertebral bodies. Gravity, muscle pull, and elastic recoil of the spread (or stretched) outer disc anulus together exert force against each of the fusion baskets. Thus the fusion baskets are held in place by compression forces between the adjacent vertebrae.

To prevent distraction froces from possibly dislodging the fusion baskets, e.g., when the patient forward flexes, thus separating the posterior margins of the adjacent vertebrae, the dorsal processes may be tied or wrapped together. By another technique, screws placed through the appropriate facet jackets limit both flexion and extension motions.

A novel interbody spreader in the form of a scissors jack has been developed to maintain a desirable parallel attitude between the adjacent vertebrae while the bore is drilled and then tapped by a novel instrument. Another instrument that has been developed for use in the implantation of the novel fusion basket is a tapping instrument for forming helical threads in a bore in recipient bone. This noval tapping instrument comprises

a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and

a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus remvoed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the the hollow shaft.

The portion of the pilot rod that projects beyond said other end of the hollow shaft preferably is threaded to carry detritus upwardly to the reservoir

When using the novel tapping instrument to form female threads for an interbody fusion, the hollow shaft should have an odd number of scallops and cutting edges, preferably three because an odd number provides more equal removal of recipient bone on both sides of the bore than would an even number.

The novel tapping instrument and a novel wrench are illustrated in the drawing that also illustrates two V-thread fusion baskets of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawing, all figures of which are schematic,

Fig. 1 is an exploded isometric view of a first V-thread fusion basket of the invention and two perforated end caps;

Fig. 2 is an isometric view illustrating the formation of a body that can be cut to form a series of second V-thread fusion baskets of the invention;

Fig. 3 is an isometric view of a tap (partly cut away to reveal details of construction) for forming female thread in bores into which a V-thread fusion basket is to be inserted; and

Fig. 4 is an isometric view of a wrench for screwing a V-thread fusion basket into a threaded hore

The fusion basket 10 of Fig. 1 was formed from a solid steel cylinder by drilling eight small, equally-spaced holes 11 in the axial direction, each hole being centered on a circle concentric with the axis of the cylinder. Then a large hole was drilled centered on the axis and having a radius substantially identical to that of the aforementioned circle. A V-thread 12 was then machined in the external surface of the cylinder, thus opening through that surface a perforation 13 extending through the rounded valley 14 of the V-thread at each crossing of the valley and one of the small holes 11. A screw thread 15 was then machined in the internal surface of the fusion basket to threadably receive an end cap 16 that has apertures 18 similar to those of a salt shaker. Snap-on end caps would also be useful.

In making a fusion basket by the technique described in the preceding paragraph, the small holes 11 could be enlarged to intersect each other, thus making it unnecessary to drill a central hole. Enlarged small holes would result in larger perforations 13.

Referring to Fig. 2, a series of fusion baskets can be made from a plurality of rods 22 of rectangular cross-section that can be continuously extruded and fed into each of eight keyways 23 in the surface of a mandrel 24. Simultaneously, a rod 26 of triangular cross-section is extruded, wrapped helically around the rectangular rods 22, and soldered or welded to each of the rectangular rods 22 at every crossing to provide an external V-thread. Upon emerging from the keyways, the resulting body is cut into individual fusion baskets each of which has a perforation 28 between adjacent turns of the V-thread-forming rod 26 wherever it bridges a gap between adjacent rectangular rods 22.

A fusion basket identical to that of Fig. 2 can be made from a hollow cylinder by machining an external V-thread and broaching a plurality of rectangular internal keyways.

Each of the fusion baskets of Figs. 1 and 2 could be made from a model by the lost-wax process.

The tapping isntrument 30 of Fig. 3 has a hollow cylindrical shaft 31 with a T-handle 32 at one end and an external thread 33 at the other end.

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Slidably received within the hollow shaft is a pilot rod 34, one end 35 of which protrudes beyond the hollow shaft 31 and slidably fits into a bore that has been drilled into the recipient bone. At the other end of the pilot rod is a knurled cap 35A. Projecting from the threaded end of the hollow shaft 31 are cutting teeth 36 that enlarge the bore to the minor diameter of the external thread 33 of the hollow shaft 31. The threaded end of the hollow shaft also is formed with three symmetrical scallops 37 (one shown) to expose a cutting edge 38 at the leading edge of the external thread 33, which cutting edge forms female bone threads in the bore upon rotation of the hollow shaft.

Detritus created by tapping instrument 30 is deposited through the scallops 37 into a reservoir provided by a central recess 39 in the pilot rod 34. The end 35 of the pilot rod which extends from the recess 39 into the bore has external threads which, when the threaded pilot rod 34 is turned, carry detritus upwardly to be deposited through the scallops into the reservoir.

Upon rotating the hollow shaft 3I to form female bone threads in the bore, the surgeon can feel increased back pressure when the reservoir becomes full and should grasp the knurled cap 35A to remove and clean out the pilot rod. If the gummy nature of the detritus were to prevent the pilot rod from being easily pulled out of the hollow shaft, the knurled cap 35A could be removed to permit the hollow shaft 31 to be unscrewed from the threaded bore, leaving the pilot rod in place. The pilot rod then serves. as a guide if the bore has not yet been completely tapped and it is necessary to reinsert the hollow shaft to complete the tapping.

The wrench 40 of Fig. 4 has a cylindrical shaft 41 with a T-handle 42 at one end and an octagonal protuberance 44 at the other end. The corners of the protuberance 44 fit into recesses in the fusion basket to permit the fusion basket to be rotated by rotating the wrench. A spring-loaded ball 46 frictionally holds the protuberance in place when it is inserted into the fusion basket.

Implanting the Fusion Basket

In order to implant the novel fusion basket between adjacent vertebrae, soft, collagenous disc material is first removed from the intervertebral space. A small window is created in the overlying laminas of each side, namely, standard laminotomies. The neural tissues, dural sac and nerves, are retracted medially. The intervertebral space is cleaned of disc material in a standard surgical fashion. If the disc space has narrowed as a result

of degeneration, a scissors-jack type vertebral spreader or a hydraulically inflated bladder is inserted on one (the first) side inside the disc space and opened until the space approximates the normal. This may be confirmed by a lateral x ray. The height of the disc space is measured on the x ray so that the proper sizes of drills, tap, and fusion basket may be chosen.

The opposite (second) side of the same disc space is then addressed. The nerve tissues on the first side are relaxed and then retracted medialward on the second side. A pilot drill (e.g., 5 mm or 8 mm diameter depending upon discal space height) cuts a small channel in the face of each of the vertebrae, penetrating the interdiscal space to a depth of about mm (the normal disc space is about 30 mm deep and 50 mm wide). A drill stop may be applied to the drill to prevent overboring the hole. A solid rod pilot is then inserted into the pilot hole and a pilot cutter (7 mm or 10 mm) is passed over it and brought downward to enlarge the pilot channels to slidably receive the pilot rod 35 of the tapping instrument 30 of Fig. 3. The cutting thread 33 (12 mm or 16 mm major diameter) cuts female bone threads through the opposing vertebral end plates and into both cancellous regions that will invite the ingrowth of new bone.

A V-thread fusion basket of the invention, with one end cap in place, is snapped onto the wrench 40 of Fig. 4 by which it is screwed by hand into the threaded intradiscal bore to its full depth. After removing the wrench, the basket is packed with bone chips or other bone-inducing substance, and the second end cap is applied to hold the bone chips securely in place.

After removing the vertebral spreader, the dura and nerves on the second side are relaxed and attention is once again directed to the first side which is drilled and tapped to receive a second fusion basket by the same procedure.

Over a period of several weeks, the bone from the vertebral bodies will grow through the perforations in the fusion baskets and unite with the boneinducing substance inside them, creating a solid fusion.

It is believed that the novel fusion baskets will primarily be implanted by a posterior approach to the spine, although an anterior approach may be utilized, especially when applied to the cervical spine.

Example 1

The fusion basket of Fig. 1 has been machined from a cylinder of surgically implantable stainless steel to have the following dimensions:

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2.8 mm

diameter of starting cylinder 16 mm lenath of cylinder diameter of each small hole 11 3 mm diameter of circle on which holes 11 are centered 11.5 mm diameter of central hole 11 mm pitch of V-thread 12 2.5 mm/turn angle at crown of thread 12 60 fillet radius in valley of thread 12 0.4 mm axial width of perforations 13 1.6 mm

when projected onto interior of a cylinder, % of

circumferential breadth of perfs. 13

area perforated 25%

A V-thread fusion basket identical in appearance to one produced as in Fig. 2 can be made from a hollow cylindrical tube. After machining an external thread, a plurality of rectangular keyways are broached in the inner surface to form perforations through the valley of the thread. A continuous technique for making a novel fusion basket starts with a continuous helical spring made from a triangular rod such as the rod 26 used in Fig. 2, then welding or soldering the inner-facing surface of the spring to a plurality of cylindrical wires, each extending parallel to the axis of the spring.

Claims

- 1. A fusion cage which is a hollow perforate rigid cylinder that can be surgically inserted into a bore that has been formed in two adjacent bony structures and filled and packed with bone chips, thus inviting ingrowth of live bone, wherein the improvement comprises: the fusion cage (a) has an extenal, substantially continuous helical V-thread by which it can be screwed into mating female threads formed in the bore and (b) is perforated in the valley between adjacent turns of the thread.
- 2. A fusion cage as defined in claim 1 wherein the V-thread is continuous and the angle at the crown of the V-thread is no more than 90°, but not less than 45°.
- 3. A fusion cage as defined in claim 2 wherein the angle at the crown of the V-thread is about 60° .
- 4. A fusion cage as defined in claim 2 wherein the V-thread has from 3 to 8 turns per cm.
- 5. A fusion cage as defined in claim 2 wherein the valley of the V-thread has a fillet, the radius of which is from 0.35 to 0.75 mm.
- 6. A fusion cage as defined in claim 1 wherein, when the surface of the fusion cage is projected onto the inner face of a cylinder, the perforations comprise from 30% to 60% of the projected area.
- 7. A fusion cage as defined in claim 1, which is fitted with removable perforated end caps.
 - 8. A fusion cage as defined in claim 1, the

major diameter of which is from 12 to 16 mm.

- A fusion cage as defined in claim 1, made of implantable-grade stainless steel.
- A fusion cage as defined in claim 1, made of biodegradable material.
- 11. A fusion cage as defined in claim 1, made of x-ray-transparent material.
- 12. A fusion cage that is a hollow rigid cylinder that is suitable for insertion during surgery into a bore that has been formed in adjacent bony structures and can contain bone inducing substances, thus inviting ingrowth of live bone, the fusion cage having an external, substantially continuous screw thread by which it can be screwed into mating female threads formed in the bore, and, having openings in the valley between turns of the thread.
- 13. A fusion cage as claimed in claim 12 having any one or more of the features as defined in claims 2 to 11.
- 14. A fusion cage as claimed in claim 12 or 13, wherein the screw thread is a V-thread.
- 15. A fusion cage as claimed in any one of the preceding claims for use in fusing adjacent bony structures
- 16. A tapping instrument comprising a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus removed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the hollow shaft.

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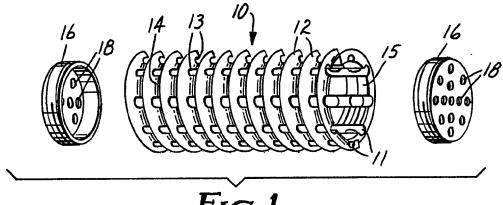
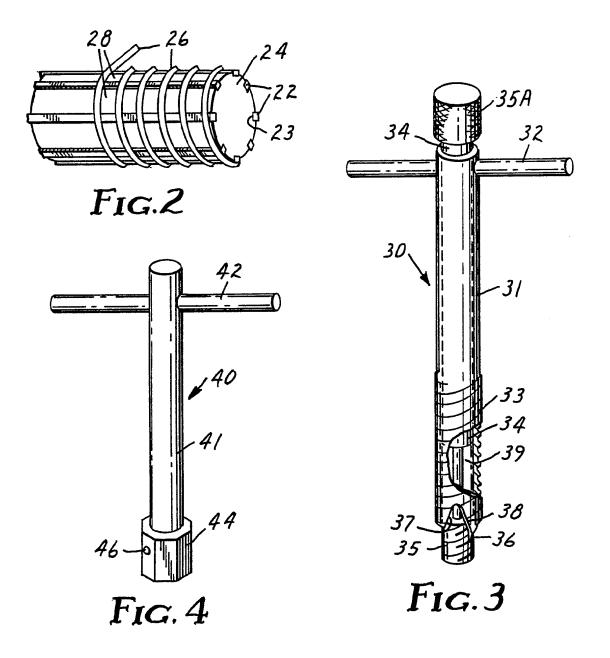


Fig.1





EUROPEAN SEARCH REPORT

EP 89 31 0572

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| Category | of relevant pa | ndication, where appropriate, ssages | to claim | CLASSIFICATION OF THE APPLICATION (Int. Cl. 5) |
| D,Y | US-A-4 501 269 (BA * Complete document | | 1,7,9, 10,12, 15 | A 61 F 2/44 |
| Y | DE-A-3 505 567 (VI * Claims; figures * | CH) | 1,7,9, 10,12, 15 | |
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